GUIDELINES FOR CERTIFICATE OF FREE SALE

Some countries require the issuance of a "Certificate of Free Sale," or other times called "Certificate for Export" or "Certificate to Foreign Governments." These requests are seeking assurances from a governmental agency that these products offered for entry into their country comply with the requirements of the U.S. laws for distribution in our domestic commerce.

U.S. and state agencies do not provide the degree of continuous supervision that would be required for the certification of unqualified assurances that a particular product complies with the laws of the U.S. and state. Several state and federal agencies will assist in the development of exports through the issuance of Certificates of Free Sale, based on their individual guidelines.

The following agencies can provide assistance and guidance in receiving Certificates of Free Sale for international shipments. The issuance of the certificates requires that the products comply with the appropriate agencies' regulations and guidelines.

US Food and Drug Administration

CRITERIA NEEDED WITH REQUEST FOR CERTIFICATE OF FREE SALE FOR DIETARY SUPPLEMENT(S), INFANT FORMULA(S), & MEDICAL FOOD(S)

(Certificates are only issued for products manufactured in the United States.)

- 1. Letter requesting certificate of free sale.
- 2. List product or products.
- 3. List the country or countries certificate of free sale is going to.
- 4. State how many certificates you are requesting.
- 5. State whether you want all products together on each certificate, or one product on a separate certificate.
- 6. Original label or labels for each product. (Note: No photocopies unless product is distributed in BULK FORM ONLY; if labeling is in a foreign language, we need the label/labels in English; the labels must be flat, do not send round containers with label applied).
- 7. The cost per certificate is \$10.00. You do not have to mail the \$10.00; you will be billed.
- 8. Mail all submissions to:

Certificate Program

Food and Drug Administration

Office of Nutritional Products, Labeling, and Dietary Supplements, HFS-810

200 C Street, S.W.

Washington, D.C. 20204

Note: There is no need to mail the request to anyone's attention as long as you have the office's certificate program mail code as listed above.

The Certificate of Free Sale is issued on official Department of Health and Human Services (DHHS) letterhead along with a DHHS seal, and cannot be notarized.

Current processing time is approximately 8 weeks.

If you have any questions please feel free to call (202) 205-5106 (Vincent Keys) or (202) 205-4605.

Web site: http://www.cfsan.fda.gov/~dms/ds-cert.html

FOOD AND SUPPLEMENTS FOR HUMAN CONSUMPTION, AND COSMETICS

Or for products manufactured in Colorado, you may contact:

Consumer Protection Division, Colorado Department of Health

4300 Cherry Creek Dr. S. Denver, Colorado 80222 Attn: Susan Parachini

Telephone: (303) 692-3646 Fax: (303) 753-6809

ANIMAL FEED AND FEED SUPPLEMENTS PRODUCED IN COLORADO

Colorado Department of Agriculture, Feed Program
2331 W. 31st Ave.
Denver, CO 80211
Attn: Chandra Hardwick

Telephone: (303) 477-0081 Fax: (303) 480-9236

WINE AND BEER

The U.S. Bureau of Alcohol, Firearms and Tobacco does not issue Certificates of Free Sale, nor have they received requests. They do issue a federal permit called a "Brewers' Notice" which could be photocopied and supplied as proof of government regulation.

MEAT

All meat exports require a USDA export inspections certificate. No Certificates of Free Sale are required when a sanitation certificate is provided.

PLANTS AND SEEDS REQUIRING PHYTOSANITARY CERTIFICATES

Colorado Department of Agriculture, Plant and Insect Section
700 Kipling St., #4000
Lakewood, CO 80215
Attn: Jerry Cochran

Telephone: (303) 239-4153 Fax: (303) 239-4177

GENERAL CERTIFICATES OF FREE SALE

In addition to the specific agencies issuing Certificates of Free Sale, a general certificate of free sale can be issued certifying that the company exists and the seller certifies that goods are freely sold from:

Rocky Mountain World Trade Center Association dba/World Trade Center Denver 1625 Broadway, #680 Denver, CO 80202

Telephone: (303) 592-5760 Fax: (303) 592-5228